REMARKS

Entry of the foregoing amendments, and further favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action summary correctly indicates that Claims 148- 158,160, 161,163 and 164 are pending and under consideration. Claims 148, 149, 151-156 and 163 have been indicated as allowable. Claims 157, 158, 160, 161 and 164 stand rejected.

Claim 150 has been objected to for containing a typographical error, but has not been otherwise rejected.

Claim 150 has been amended in accordance with the Examiner's suggestion to correct an obvious typographical error. Claim 158 has been amended to recite that the immunological effector cells are T-cells, which the Examiner has acknowledged is enabled by the specification.

No new matter has been added by the amendments. Applicants reserve the right to pursue any subject matter that has been canceled from the application in a continuation or divisional application.

Claim Objections

Claim 150 has been objected to for an obvious typographical error. The objection has been obviated by the present amendment, which corrects the error.

Written Description

The rejection of claims 157, 160, 161 and 164 under 35 U.S.C. 1 12, first paragraph, as allegedly failing to comply with the written description requirement has been maintained for the reasons of record. The claims have been alleged to contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is traversed.

The Examiner has reiterated the assertion that the products of claims 157, 160, 16 1 and 164 lack adequate written description, on the principle that the specification cannot adequately describe cells which have yet to be isolated. The Examiner further asserts that applicants arguments in response to this assertion have, so far, been unpersuasive because

allegedly "the isolation of the CTL as the final product are not adequately described because the endogenous epitopes associated with impaired cellular peptide processing cannot be controlled or predicted or described by the process."

Applicants respectfully submit that it is not necessary for the structure of any particular endogenous epitopes associated with impaired cellular peptide processing to be predicted in order to describe and claim the resultant products, because all of the necessary endogenous epitopes are obtained simply by the processes of inhibiting the MHC processing machinery of the relevant presenting cells. This is the essence and beauty of the invention.

Applicants further submit that CTL that recognize such epitopes are adequately described by the process used to make them in accordance with the purpose and spirit of the provisions of patent law for which "product-by-process" claims have long been provided. It is an old principle of our patent law that novel products can be adequately described by reference to their method of manufacture. *See, e.g., Ex parte Fox*, 128 USPQ 157 (Bd. Pat. App. & Int. 1957)(" a product may be characterized by its method of production, formula, name or tests by which it may be identified apart from its method of production"). Product by process claims exist for the very reason that certain products are best described by the process used to manufacture them.

The present application sets forth a method of manufacture of the cells of claims 148, 155 and 163. Claims 157, 161 and 164 simply claim the products of those processes in the manner that has long been accepted by the patent office. *See, e.g., Ex parte Robinson*, 102 U.S.P.Q. 219, 221 (Bd. Pat. App. & Int. 1952) ("The practice of defining an article of manufacture in terms of the method by which it has been produced has long been permitted by the Patent Office where . . . it is not possible to adequately define the article or product by reciting physical and chemical characteristics.") The predecessor of the Federal Circuit explained "In order to be patentable, a product must be novel, useful and unobvious. In our law, this is true whether the product is claimed by describing it, or by listing the process steps used to obtain it." *In re Brown and Saffer*, 173 USPQ 685 (C.C.P.A. 1972). It is noted that claims to antibodies that are routinely issued by the patent office are held to be adequately described on a similar basis. Antibodies are claimed by reference to the target used to manufacture them and to which they bind. The patent office does not require a description of the particular sequence or structure of the antibody's binding site which cannot be predicted.

Therefore, according to long standing principles of patent law, the subject matter of claims 157, 161 and 164 is adequately described by the process of manufacture set forth in claims 148, 155 and 163, respectively. Claim 160 recites a composition comprising the cells produced by the method of manufacture set forth in claim 148 or the antigens or epitopes that can be isolated from those cells. The antigens and epitopes expressed by the cells manufactured according to the method of claim 148 are inherent products of that method of manufacture. Thus, those elements of claim 160 are inherently described by the method of manufacture according to claim 148.

Because the patent office has long held that a product may be adequately described by its method of manufacture even if the precise chemical structure of the product cannot be described, and the method of manufacture has been adequately described, the rejection of claims 157, 160, 161 and 164 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Enablement

Claim 158 stands rejected under 35 U.S.C. 1 12, first paragraph, because the specification has been alleged not to reasonably provide enablement for a method of administering effector cells which are not T cells. The Examiner has acknowledged that the specification is enabling for a method comprising administering to a mammal T cells that selectively recognize cells showing TAP deficient processing of peptides for MHC class I presentation.

Without agreeing with the alleged basis of the rejection, and simply to expedite prosecution of subject matter that has been acknowledged as satisfying the enablement requirement, claim 158 has been amended to recite that the recited effector cells are T-cells. Accordingly, the rejection has been obviated.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: March 13, 2008

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